IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

THE SECURITY NATIONAL BANK OF SIOUX CITY, IOWA, as conservator for J.M.K., a Minor, PLAINTIFF, **v.** **ABBOTT LABORATORIES,** DEFENDANT	**Case No. 5:11-cv-04017-DEO** **DEFENDANT ABBOTT LABORATORIES' ANSWER TO THE SECOND AMENDED COMPLAINT**

PREFACE

Abbott specifically denies the existence of, or its participation in, any wrongdoing as alleged in the Complaint. Abbott further denies each and every allegation contained in the Complaint, except as specifically admitted. Any factual averment admitted is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendoes or speculations contained in any averment or in the Complaint as a whole. Moreover, Abbott specifically denies any allegations contained in the headings or unnumbered paragraphs in the Complaint. TAP also denies all allegations that contain legal arguments or conclusions of law as well as those allegations that do not require a response.

These comments and objections are incorporated into each numbered paragraph of Abbott's Answer.

I. PARTIES, JURISDICTION AND VENUE

1. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 1, and therefore denies them.

2. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 2, and therefore denies them.

3. Abbott admits the allegations of the first sentence of paragraph 3.

4. Abbott admits that it manufactures Similac® powdered infant formula, but denies that it manufactures any powdered infant formula in Iowa. All remaining allegations not specifically admitted are denied.

5. Abbott admits that CT Corporation is its registered agent in the State of Iowa.

6. Abbott admits the allegations of paragraph 6.

7. Abbott admits that there is diversity of citizenship between the parties and that plaintiff alleges damages in excess of $75,000.00.

8. The allegations contained in paragraph 8 constitute legal argument and conclusions and are therefore denied. Abbott denies that any alleged action or omission on its part occurred in the Northern District of Iowa.

II. GENERAL FACT ALLEGATIONS

9. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 9, and therefore denies them.

10. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 10, and therefore denies them.

11. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 11, and therefore denies them.

12. Abbott denies the allegations contained in the first sentence of paragraph 12. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 12, and therefore denies them.

13. Abbott admits that included on the label of its Similac® NeoSure® powdered infant formula were directions for its preparation and use along with warnings and precautions for the product, including, but not limited to the quoted text and a warning that powdered infant formulas are not sterile. Abbott further states that its labeling is in keeping with FDA regulations and requirements as well as Codex's code of practice. Further answering, Abbott states that the entire contents of such warnings and precautions have not been cited in paragraph 13. All remaining allegations not specifically admitted are denied.

14. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 14, and therefore denies them.

15. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 15, and therefore denies them.

16. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 16, and therefore denies them.

17. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 17, and therefore denies them.

18. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 18, and therefore denies them.

19. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 19, and therefore denies them.

20. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 20, and therefore denies them.

21. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 21, and therefore denies them.

22. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 22, and therefore denies them.

23. Abbott denies that its product contained *Enterobacter sakazakii* ("*E. sak*") and denies that its product caused any harm to J.M.K. Abbott lacks information or knowledge sufficient to form a belief concerning the remaining allegations of paragraph 23, and therefore denies them.

24. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 24, and therefore denies them.

25. Abbott lacks information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 25, and therefore denies them.

26. The allegations contained in paragraph 26 constitute legal argument and conclusions and are therefore denied.

27. Denied.

28. Denied.

29. Denied.

30. Denied.

31. Denied, upon information and belief.

32. Denied.

33. Denied.

34. Denied.

35. Abbott denies that any samples of its product tested by FDA as set forth in paragraph 35 tested positive. Abbott admits that FDA tested samples of powdered infant formula from various U.S. powdered infant formula manufacturers and facilities, and that a

published report stated that a certain percentage of samples from unnamed manufacturers and facilities contained the bacteria. Further answering, Abbott states that none of those samples testing positive was an Abbott product or involved an Abbott facility.

36. Admitted, except that Abbott denies that the presence of *Enterobacteriaceae* indicates the presence of *E. sak*.

37. Denied.

38. Admitted as to one instance.

39. Abbott admits that powdered infant formula is not sterile, as sterilizing such food would reduce its nutritional value and could thereby create a public health hazard for infants, and denies any implication, intended or otherwise, in paragraph 39 that there is any requirement in any law, statute or guidance, that such food be sterile. Abbott further admits that it knew these well-known facts prior to October 2004, as did health care providers, many of the public and FDA. Abbott denies all remaining allegations in paragraph 39.

40. Denied.

41. Abbott denies the first sentence of paragraph 41, specifically that an Abbott product would go to distribution in a contaminated state given its testing and compliance procedures. Abbott admits that powdered infant formula is not commercially sterile, as only liquid formulas are, and states that sterilizing powdered formula would reduce its nutritional value and could thereby create a public health hazard for infants, and denies any implication, intended or otherwise, in paragraph 41 that there is any requirement in any law, statute or guidance, that such food be sterile. Abbott further admits that its testing and sampling procedures meet or exceed FDA and Codex standards or codes of practice, and that it follows destruction protocols accordingly. Abbott also admits that *E. sak* is not intrinsic to the product,

is not a characteristic of the product, and is not part of the intended design of the product. Abbott denies all remaining allegations of paragraph 41.

42. Denied.

43. Denied.

44. Denied.

45. The allegations contained in paragraph 45 constitute legal argument and conclusions and are therefore denied.

46. Denied.

47. Denied.

48. The allegations contained in paragraph 48 constitute legal argument and conclusions and are therefore denied.

49. Denied.

50. Abbott admits that it manufactures liquid infant formula that is commercially sterile and that prior to opening, after which it is subjected to contamination from many bacteria in the home and other environments, it does not contain *E. sak.*

51. Denied, as Dr. Janine Jason has testified.

52. Abbott admits that its liquid formula is commercially sterile as described above in its answer to paragraph 50, and denies that it is "sterile." Abbott denies that liquid formula is an alternative design to powdered infant formula, and states that only the baby's physician can determine the appropriate formula for a particular baby, after taking into account any genetic issues or specialized requirements the baby may have. Abbott admits that its infant formulas are safe, and denies any remaining allegations in paragraph 52.

53. Denied. Abbott repeats and incorporates its response to paragraph 52.

54. Denied. Abbott repeats and incorporates its response to paragraph 52.

III. CAUSES OF ACTION
COUNT 1-DEFECTS OF MANUFACTURING

55. Abbott repeats and incorporates its answers and responses to paragraphs 1-54 as its answer to paragraph 55.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

WHEREFORE, Abbott prays for judgment in its favor, for costs of suit and for all other relief this Court deems just and proper.

COUNT 2-DEFECTS OF DESIGN

61. Abbott repeats and incorporates its answers and responses to paragraphs 1-60 as its answer to paragraph 61.

62. Denied.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

WHEREFORE, Abbott prays for judgment in its favor, for costs of suit and for all other relief this Court deems just and proper.

COUNT 3 — FAILURE TO WARN

73. Abbott repeats and incorporates its answers and responses to paragraphs 1-72 as its answer to paragraph 73.

74. Denied.

75. The allegations contained in the first sentence of paragraph 75 constitute legal argument and conclusions and are therefore denied. Abbott admits that included on the label of its Similac® NeoSure® powdered infant formula were directions for its preparation and use along with warnings and precautions for the product, including, but not limited to the quoted text and a warning that powdered infant formulas are not sterile. Abbott further states that its labeling is in keeping with FDA regulations and requirements as well as Codex's code of practice. Further answering, Abbott states that the entire contents of such warnings and precautions have not been cited in paragraph 75. All remaining allegations not specifically admitted are denied.

76. Denied.

77. Denied.

78. Denied.

WHEREFORE, Abbott prays for judgment in its favor, for costs of suit and for all other relief this Court deems just and proper.

COUNT 4 — BREACH OF EXPRESS WARRANTIES

79. Abbott repeats and incorporates its answers and responses to paragraphs 1-78 as its answer to paragraph 79.

80. Abbott denies that it "distributed its product to J.M.K.," denies that paragraph 80 cites all of the language on the label, and denies that the language cited is a warranty. Abbott admits that the language cited in paragraph 80 appears on the label, is in keeping with FDA regulations and requirements as well as Codex practices, and that the label contains precautions, instructions and warnings that have not been cited or quoted. All remaining allegations not specifically admitted are denied.

81. Abbott lacks knowledge or information sufficient to admit or deny the allegations of paragraph 81 concerning whether such statement has been on its website from 2006 through the present day continuously, and has not conducted a six-year search of its website, nor is it required to do so, in order to respond to the allegations of paragraph 81. Abbott further denies that the statement is a warranty, or that it made any warranty to St. Luke's Regional Medical Center or the Kunkel parents. Abbott denies all remaining allegations in paragraph 81.

82. Abbott states that the contents of www.abbottmama.com speak for themselves, and that there is voluminous information about infant nutrition on the website now as there was in 2008. Abbott admits, as would every pediatrician and health care provider in the country and as Dr. Janine Jason has testified, that infant formula is the only safe, nutritious and recommended alternative to breastfeeding infants. Abbott denies that the statement is a warranty or that it made any warranty to St. Luke's Regional Medical Center or the Kunkel parents. Abbott denies all remaining allegations in paragraph 82.

83. Abbott lacks knowledge or information sufficient to admit or deny the contents of a press release that was not provided with the complaint, and has nothing to do with the instant

suit, and therefore denies the allegations. Abbott also denies that it made any warranty to St. Luke's Regional Medical Center or the Kunkel parents or that the allegations of paragraph 83 constitute a warranty. Abbott denies all remaining allegations in paragraph 83.

84. Abbott lacks knowledge or information sufficient to admit or deny the contents of a 2009 advertisement that was not provided with the complaint, and has nothing to do with the instant suit, and therefore denies the allegations of paragraph 84. Further answering, Abbott denies that any allegation in this paragraph is a warranty. Abbott denies all remaining allegations in paragraph 84.

85. Denied.

86. Denied.

87. Denied.

88. Denied.

89. Denied.

90. Denied.

WHEREFORE, Abbott prays for judgment in its favor, for costs of suit and for all other relief this Court deems just and proper.

COUNT 5 — [DISMISSED] BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

91. Abbott repeats and incorporates its answers and responses to paragraphs 1-90 as its answer to paragraph 91.

92. Paragraph 92 relates solely to claims dismissed with prejudice by the Court on February 1, 2012, (*see* Dkt. #64), and as such, Abbott need not and does not respond to those allegations.

93. Paragraph 93 relates solely to claims dismissed with prejudice by the Court on February 1, 2012, (*see* Dkt. #64), and as such, Abbott need not and does not respond to those allegations.

94. Paragraph 94 relates solely to claims dismissed with prejudice by the Court on February 1, 2012, (*see* Dkt. #64), and as such, Abbott need not and does not respond to those allegations.

95. Paragraph 95 relates solely to claims dismissed with prejudice by the Court on February 1, 2012, (*see* Dkt. #64), and as such, Abbott need not and does not respond to those allegations.

96. Paragraph 96 relates solely to claims dismissed with prejudice by the Court on February 1, 2012, (*see* Dkt. #64), and as such, Abbott need not and does not respond to those allegations.

97. Paragraph 97 relates solely to claims dismissed with prejudice by the Court on February 1, 2012, (*see* Dkt. #64), and as such, Abbott need not and does not respond to those allegations.

98. Paragraph 98 relates solely to claims dismissed with prejudice by the Court on February 1, 2012, (*see* Dkt. #64), and as such, Abbott need not and does not respond to those allegations.

99. Paragraph 99 relates solely to claims dismissed with prejudice by the Court on February 1, 2012, (*see* Dkt. #64), and as such, Abbott need not and does not respond to those allegations.

100. Paragraph 100 relates solely to claims dismissed with prejudice by the Court on February 1, 2012, (*see* Dkt. #64), and as such, Abbott need not and does not respond to those allegations.

COUNT 6— BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

101. Abbott repeats and incorporates its answers and responses to paragraphs 1-100 as its answer to paragraph 101.

102. The allegations of paragraph 102 contain legal arguments and conclusions and are therefore denied.

103. Denied.

104. Denied.

105. Denied.

106. Denied.

107. Denied.

108. Denied.

WHEREFORE, Abbott prays for judgment in its favor, for costs of suit and for all other relief this Court deems just and proper.

COUNT 7— FRAUD

109. Abbott repeats and incorporates its answers and responses to paragraphs 1-108 as its answer to paragraph 109.

110. Abbott repeats and incorporates its answer to paragraph 81 as its answer to paragraph 110 as though fully set forth. Abbott denies all remaining allegations in paragraph 110.

111. Abbott repeats and incorporates its answer to paragraph 82 as its answer to paragraph 111 as though fully set forth. Abbott denies all remaining allegations in paragraph 111.

112. Abbott repeats and incorporates its answer to paragraph 83 as its answer to paragraph 112 as though fully set forth. Abbott denies all remaining allegations in paragraph 112.

113. Abbott repeats and incorporates its answer to paragraph 84 as its answer to paragraph 113 as though fully set forth. Abbott denies all remaining allegations in paragraph 113.

114. Abbott repeats and incorporates its answer to paragraph 82 as its answer to paragraph 114 as though fully set forth. Abbott denies all remaining allegations in paragraph 114.

115. Abbott admits that included on the label of its Similac® NeoSure® powdered infant formula were directions for its preparation and use along with warnings and precautions for the product, including, but not limited to the quoted text and a warning that powdered infant formulas are not sterile. Abbott further states that its labeling is in keeping with FDA regulations and requirements as well as Codex's code of practice. Further answering, Abbott states that the entire contents of such warnings and precautions have not been cited in paragraph 115. All remaining allegations not specifically admitted are denied.

116. Denied.

117. Denied.

118. Denied.

119. Denied.

WHEREFORE, Abbott prays for judgment in its favor, for costs of suit and for all other relief this Court deems just and proper.

PRAYER FOR RELIEF

120. Denied.

WHEREFORE, Abbott prays for judgment in its favor, for costs of suit and for all other relief this Court deems just and proper.

AFFIRMATIVE AND OTHER DEFENSES

By asserting the defenses set forth below, Abbott does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these defenses or that plaintiff is relieved of its burden to prove each and every element of its claims and the damages, if any, to which it alleges it is entitled. As for its affirmative and other defenses, Abbott reasserts and reincorporates as if fully set forth below its responses to paragraphs 1 through 120 above.

FIRST DEFENSE

The Complaint, and each purported cause of action, fails to state a cause of action against Abbott for which relief can be granted.

SECOND DEFENSE

The Complaint, and each purported cause of action, is barred by the applicable statutes of limitations.

THIRD DEFENSE

Plaintiff's claims are barred by the learned intermediary doctrine. Specifically, Abbott alleges that it provided adequate information to the medical community, and that the medical community, in turn, has information as to potential risks, if any, with the use of Similac ® NeoSure® powdered infant formula. Reasonable health-care providers in the medical

community, knowing of such potential risks and benefits, would still, and did, recommend the subject product for plaintiff.

FOURTH DEFENSE

Abbott alleges that Plaintiff's products liability claims are barred by sections of the *Restatement (Third) of Torts: Product Liability*. Among other facts supporting its defenses under the Restatement, Abbott's product complied with all applicable premarket approval processes, product safety statutes and administrative regulations. Furthermore, the potential risks, if any, posed by Abbott's product are outweighed by its foreseeable benefits, and reasonable healthcare providers, knowing of such potential risks and therapeutic benefits, would still, and did, recommend the subject product for plaintiff.

FIFTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the subject product was designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge. Abbott invokes all state of the art defenses applicable to plaintiff's claims, including the state of the art applicable to the industry in question, medicine, medical science and all others, alleging that it discharged, according to law and due care, each and every duty which it may have owed.

SIXTH DEFENSE

Abbott alleges that the subject product was manufactured under conditions and procedures and with products as used by other reputable manufacturers of such products and complied with the standards of the industry as of the time of manufacture. Such products were safe for their intended use and were not defective or unreasonably dangerous.

SEVENTH DEFENSE

Plaintiff's claims for damages seek recovery for an alleged defect in the subject product that was beyond the state of the art for its manufacture and the warnings that applied to its use.

EIGHTH DEFENSE

Plaintiff's claims are expressly and impliedly preempted, in whole or in part, by the statutes and Constitution of the United States, including the Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 *et seq.*, under the Supremacy Clause of the United States Constitution. Specifically, the conduct of Abbott in all activities with respect to the subject product has been and is under the supervision of the United States Food and Drug Administration ("FDA") and plaintiff's claims would thwart and undermine the implementation of federal policies.

NINTH DEFENSE

Abbott was in compliance with all federal and state laws and regulations existing at the relevant time and relating to the manufacture of Similac® NeoSure®, including all standards for labeling, warning, or instructions. As a result, Abbott's product, Similac® NeoSure®, is not unreasonably dangerous under Iowa law.

TENTH DEFENSE

Plaintiff's claims premised upon breach of warranty are governed, and limited by, the provisions of the Uniform Commercial Code as codified in Iowa Code Section 554.

ELEVENTH DEFENSE

If plaintiff experienced any reaction from ingesting Similac® NeoSure®, such reaction was neither intended, nor reasonably foreseeable, at the time the product left Abbott's control.

TWELFTH DEFENSE

If plaintiff experienced any reaction from ingesting Similac® NeoSure®, Abbott had no duty to warn of such a reaction because the product was not dangerous to the extent beyond which would be contemplated by the ordinary user with the ordinary knowledge common to the community, or because the user knew or reasonably should be expected to know of the characteristic of the product that may cause the danger.

THIRTEENTH DEFENSE

If plaintiff has suffered or will suffer damages as alleged in the complaint, such damages have been and will be proximately caused, in whole or in part, by the comparative fault of persons or entities for whose conduct Abbott is not responsible. To that extent, plaintiff's recovery, if any, should be reduced by the comparative fault, negligence, responsibility, or causation attributable to one or more third parties, over whom Abbott had no control and for whom Abbott is not liable.

FOURTEENTH DEFENSE

If plaintiff has suffered or will suffer damages as alleged in the complaint, such damages have been and will be proximately caused, in whole or in part, by the comparative fault of plaintiff. To that extent, plaintiff's recovery, if any, should be reduced by its comparative fault, negligence, responsibility.

FIFTEENTH DEFENSE

If plaintiff suffered or will suffer any damages as alleged in the complaint, such damages were aggravated by plaintiff's failure to use reasonable diligence to mitigate such damages. To that extent, recovery on the complaint against Abbott is barred or diminished.

SIXTEENTH DEFENSE

If plaintiff sustained any injuries or incurred any damages as alleged in the complaint, such injuries and damages, if any, were the result of intervening or superseding events, factors, occurrences, or conditions which were in no way caused by Abbott, and for which Abbott is neither responsible nor liable.

SEVENTEENTH DEFENSE

At the time Abbott's Similac® NeoSure® left Abbott's control, it was accompanied by adequate warnings.

EIGHTEENTH DEFENSE

Plaintiff's alleged injuries and damages, if any, proximately resulted from the modification, alteration, misuse, abnormal use, abuse, unintended and/or unforeseeable use of Abbott's powdered infant formula and consequently no act or omission on the part of Abbott proximately caused any of plaintiff's claimed injury or damages.

NINETEENTH DEFENSE

If plaintiff suffered or will suffer any damages as alleged in the complaint, such damages is barred or reduced by plaintiff's knowing, voluntary, and/or willful assumption of risk of any injury by not heeding the precautions or warnings provided with the subject product.

TWENTIETH DEFENSE

Recovery on the complaint, and each purported cause of action contained therein, is barred by the doctrines of laches, waiver and estoppel because plaintiff delayed an unreasonable period of time before asserting the claims alleged in the complaint, causing detriment and prejudice to Abbott.

TWENTY FIRST DEFENSE

Plaintiff's prayer for punitive damages violates the Fifth, Sixth, Seventh, Eighth and Fourteenth Amendments of the U.S. Constitution.

TWENTY SECOND DEFENSE

Plaintiff's prayer for punitive damages violates the Due Process and Equal Protection Clauses of the Iowa constitution.

TWENTY THIRD DEFENSE

Any alleged acts or omissions of Abbott were undertaken in good faith and without malice or recklessness, and were fully justified and reasonable under the circumstances.

TWENTY FOURTH DEFENSE

The product of which plaintiff complains has certain unavoidable, inherent characteristics which cannot be obviated under the state of scientific knowledge existing at the time such products were manufactured. While denying that such characteristics are dangerous or defective, if plaintiff sustained any injuries as a result of using or exposure to the product at issue, those injuries were the result of properties necessarily associated with the product that were unavoidable and for which Abbott cannot be held responsible.

TWENTY FIFTH DEFENSE

The public interest and benefit in the availability of such product that is the subject matter of this action preclude liability for any risks, if any resulting from such activities, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to plaintiff's claims, if it determined that there is a risk inherent in the said product, then such risk, if any, is outweighed by the benefit of the product.

TWENTY SIXTH DEFENSE

Plaintiff's losses, if any, are subject to an off-set in the amount of any reimbursement received by plaintiff as a result of any insurance or other health benefit plan, or any amounts paid for by any insurance of other health benefits plan.

TWENTY SEVENTH DEFENSE

Abbott denies any misrepresentation and/or fraud on its part, and/or reliance by plaintiff and detriment to plaintiff allegedly resulting therefrom.

TWENTY EIGHTH DEFENSE

Abbott has not knowingly or intentionally waived any applicable affirmative defenses and reserves the right to assert and rely on such other applicable affirmative defenses as may become available or apparent during the course of the litigation. Abbott further reserves the right to amend its answer and/or its affirmative defenses accordingly.

WHEREFORE, Abbott prays for judgment in its favor and against plaintiff, for Abbott's costs, and for such other relief as this Court deems just and proper.

JURY DEMAND

Abbott demands a trial by jury.

Dated: February 28, 2012

Respectfully submitted,

s/ Gabriel H. Scannapieco

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CERTIFICATE OF SERVICE

I, Gabriel H. Scannapieco, certify that on the 28th day of February, 2012, I served the foregoing via electronic delivery to all parties that have filed an appearance in this matter at their e-mail addresses on file with the Court.

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